AMENDMENTS TO THE CLAIMS

1. (Canceled)

2. (Currently Amended) The method according to claim 59, wherein ~~A method for the preparation of a pharmaceutical particulate composition for modified release of one or more therapeutically, prophylactically and/or diagnostically active substances, the method comprising~~
~~i) spraying a first composition comprising an oily material, which has a melting point of about 5 °C or more on a second composition comprising a material in solid form, the second composition having a temperature of at the most a temperature corresponding to the melting point of the oily material and/or of the first composition,~~
~~ii) optionally, mixing or other means of mechanical working the second composition onto which the first composition is sprayed to obtain a particulate material,~~
~~iii) adding one or more release-rate modifier modifiers by dry mixing, and~~
~~iv) mixing or other means of mechanical working the second composition--including, the added one or more release-rate modifying substances--onto which the first composition is sprayed to obtain a particulate composition,~~ the ~~particulate~~ composition comprises ~~comprising~~ a sufficient amount of at least one release-rate modifier to provide a modified release of the tacrolimus ~~active substance~~ sufficient to provide a dissolution rate in vitro of the ~~particulate~~ composition, ~~which~~ which when measured according to USP dissolution test (paddle) employing water as dissolution medium, 100 rpm and a temperature of about 37 °C permits release of less than 85% w/w within about 30 min after start of the test.

3. (Currently Amended) The ~~A~~ method according to claim 2, wherein less than about 80% w/w is released within about 30 min after start of the test.

4. (Currently Amended) The ~~A~~ method according to claim 2, wherein less than 85% w/w is released within about 6 hours after start of the test.

5. (Currently Amended) The ~~A~~ method according to claim 4, wherein less than 80% w/w is released within the first hour after start of the test.

6. (Currently Amended) The ~~A~~ method according to claim 4, wherein less than 80% w/w is released within 2 hours after start of the test.

7. (Currently Amended) The ~~A~~ method according to claim 4, wherein less than 80% w/w is released within 3 hours after start of the test.

8. (Currently Amended) The ~~A~~ method according to claim 4, wherein less than 80% w/w is released within 6 hours after start of the test.

9. (Currently Amended) The ~~A~~ method according to claim 2, wherein less than 75% w/w is released within about 10 hours after start of the test.

10. (Currently Amended) The ~~A~~ method according to claim 9, wherein less than 70% w/w is released within about 10 hours after start of the test.

11. (Currently Amended) The ~~A~~ method according to claim 9, wherein more than 20% w/w within about 10 hours after start of the test.

12. (Currently Amended) The ~~A~~ method according to claim 2, wherein more than 20% w/w is released within about 15 hours after start of the test.

13. (Currently Amended) The method according to claim 59, wherein ~~A method for the preparation of a pharmaceutical particulate composition for modified release of one or more therapeutically, prophylactically and/or diagnostically active substances, the method comprising~~

~~i) spraying a first composition comprising an oily material, which has a melting point of about 5 °C or more and which is present in the first composition in liquid form, on a second composition comprising a material in solid form, the second composition having a temperature of at the most a temperature corresponding to the melting point of the oily material and/or of the first composition,~~
~~ii) optionally, mixing or other means of mechanical working the second composition onto which the first composition is sprayed to obtain a particulate material,~~
~~iii) adding one or more release-rate modifier by dry mixing, and~~
~~iv) mixing or other means of mechanical working the second composition--including, the added one or more release-rate modifying substances--onto which the first composition is sprayed to obtain a particulate composition,~~ the ~~particulate~~ composition ~~comprising~~ comprises a sufficient amount of at least one release-rate modifier so that, when the composition is ingested by a mammal, ~~following ingestion by a subject in need thereof~~ the active substance is released in the gastrointestinal tract of the mammal at a rate so that less than 85% w/w is released within the first 30 min after ingestion.

14. (Currently Amended) The ~~A~~ method according to claim 13, wherein less than about 80% w/w is released within about 30 min after ingestion.

15. (Currently Amended) The ~~A~~ method according to claim 13, wherein less than 85% w/w is released within about 6 hours after ingestion.

16. (Currently Amended) The ~~A~~ method according to claim 15, wherein less than 80% w/w is released within the first hour after ingestion.

17. (Currently Amended) The ~~A~~ method according to claim 15, wherein less than 80% w/w is released within 2 hours after ingestion.

18. (Currently Amended) The ~~A~~ method according to claim 15, wherein less than 80% w/w is released within 3 hours after ingestion.

19. (Currently Amended) The ~~A~~ method according to claim 15, wherein less than 80% w/w is released within 6 hours after ingestion.

20. (Currently Amended) The ~~A~~ method according to claim 13, wherein less than 75% w/w is released within about 7 hours after ingestion.

21. (Currently Amended) The ~~A~~ method according to claim 20, wherein less than 70% w/w or less than about 65% w/w is released within about 7 hours after ingestion.

22. (Currently Amended) The ~~A~~ method according to claim 13, wherein more than 20% w/w within about 10 hours after ingestion.

23. (Currently Amended) The ~~A~~ method according to claim 13, wherein more than 20% w/w is released within about 24 hours after ingestion.

24.-35. (Canceled)

36. (Currently Amended) A method according to claim [[1]] 59, wherein the particles ~~particulate material~~ obtained have ~~has~~ a geometric weight mean diameter d_{gw} of ≥10 μm.

37.-38. (Canceled)

39. (Currently Amended) The ~~A~~ method according to claim 59 ~~according to claim 1~~, wherein the method is carried out in a high or low shear mixer or in a fluid bed.

40. (Currently Amended) The ~~A~~ method according to claim 59 ~~according to claim 1~~, wherein the process is carried out in a fluid bed ~~and the spraying of the first composition is performed on the second composition in a fluidized state~~.

41. (Currently Amended) The ~~A~~ method according to claim 59 ~~according to claim 40~~, wherein the spraying is performed through a spraying device equipped with temperature controlling means.

42. (Canceled)

43. (Currently Amended) The ~~A~~ method according to claim 59 ~~according to claim 1~~, wherein the concentration of the oily material in the particulate material is from about 5 to about 95% v/v.

44. (Canceled)

45. (Currently Amended) The ~~A~~ method according to claim 59 ~~according to claim 1~~, wherein the first composition in liquid form has a viscosity (Brookfield DV-III) of at most 800 mPas at a temperature of at the most 100 °C.

46. (Currently Amended) The ~~A~~ method according to claim 59 ~~according to claim 2~~, wherein the first composition is essentially non-aqueous and it contains at most 20% w/w water.

47. (Currently Amended) The ~~A~~ method according to claim 59, ~~according to claim 1,~~ wherein the oily material has a melting point of at least 30 °C.

48. (Currently Amended) The ~~A~~ method according to claim 59 ~~claim 1~~, wherein the oily material has a melting point of at most 300 °C.

49. (Currently Amended) The ~~A~~ method according to claim 59 ~~claim 1~~, wherein the first composition comprises one or more pharmaceutically acceptable excipients.

50. (Currently Amended) The ~~A~~ method according to claim 59 ~~claim 1~~, wherein the second composition comprises one or more pharmaceutically acceptable excipients.

51. (Currently Amended) The ~~A~~ method according to claim 49, wherein the pharmaceutically acceptable excipient is selected from the group consisting of fillers, binders, disintegrants, glidants, colouring agents, taste-masking agents, pH-adjusting agents, solubilizing agents, stabilising agents, wetting agents, surface active agents, and antioxidants.

52. (Canceled)

53. (Currently Amended) The ~~A~~ method according to claim [[1]] 59, wherein the tacrolimus ~~an active substance~~ is dispersed in the first composition.

54. (Currently Amended) The ~~A~~ method according to claim [[1]] 59, further comprising a step of processing the ~~particulate composition~~ particles obtained optionally together with one or more pharmaceutically acceptable excipients into a solid dosage form.

55. (Currently Amended) The ~~A~~ method according to claim 54, wherein the solid dosage form is selected from the group consisting of tablets, capsules~~,~~ and sachets.

56. (Currently Amended) The ~~A~~ method according to claim 54, wherein the solid dosage form is provided with a coating.

57. (Currently Amended) The ~~A~~ method according to claim 56, wherein the coating is selected from the group consisting of film-coatings, modified release coatings, enteric coatings, sugar coatings and taste-masking coatings.

58. (Canceled)

59. (Currently Amended) A method for preparing a solid composition comprising tacrolimus ~~a drug substance~~ and a release-rate modifier ~~modifying substance~~, the method comprising the steps of

i) selecting a first composition comprising an oily material having a melting point of at least 5 °C,

ii) optionally bringing the first composition in liquid form,

iii) dispersing or dissolving tacrolimus ~~a drug substance~~ in the liquid first composition at a temperature below the melting point of the tacrolimus ~~the drug substance~~,

iv) spraying the resulting first composition onto a solid second composition having a temperature below the melting point of the first composition,

v) adding ~~a release-modifying substance~~ at least one release-rate modifier to the resulting composition by dry mixing,

vi) mechanically working the resulting composition to obtain particles~~, i.e. a particulate material~~, and

vii) optionally subjecting the particulate material to conventional methods for preparing solid dosage forms.

60.-65. (Canceled).

66. (Currently Amended) A ~~pharmaceutical~~ solid composition prepared by the method of claim 59. ~~according to claim 65, in the form of powders, tablets, capsules or sachets.~~

67.-70. (Canceled)

71. (New) The method according to claim 59, wherein the solid second composition comprises lactose.

72. (New) The method according to claim 59, wherein the first composition comprises (i) polyethylene glycol having an average molecular weight of from 3,000 to 35,000 and (ii) poloxamer.

73. (New) The method according to claim 59, wherein the first composition comprises PEG6000 and poloxamer 188.

74. (New) The method according to claim 59, wherein the release-rate modifier is added in a fluid bed.

75. (New) The method according to claim 59, wherein the release-rate modifier is hydroxypropyl methylcellulose.

76. (New) The method according to claim 72, wherein the release-rate modifier is hydroxypropyl methylcellulose.

77. (New) The method according to claim 73, wherein the release-rate modifier is hydroxypropyl methylcellulose.

78. (New) The method according to claim 74, wherein the release-rate modifier is hydroxypropyl methylcellulose.

79. (New) The method according to claim 76, wherein the polyethylene glycol, poloxamer, and hydroxypropyl methylcellulose form a matrix.

80. (New) The method according to claim 77, wherein the polyethylene glycol, poloxamer, and hydroxypropyl methylcellulose form a matrix.

81. (New) The method according to claim 59, wherein the concentration of release-rate modifier is from about 10 to about 60% w/w.

82. (New) The method according to claim 75, wherein the concentration of release-rate modifier is from about 10 to about 60% w/w.

83. (New) A solid composition prepared by the method of claim 72.

84. (New) A solid composition prepared by the method of claim 73.

85. (New) A solid composition prepared by the method of claim 74.

86. (New) A method for preparing a solid dosage form comprising tacrolimus, the method comprising the steps of

i) dispersing or dissolving tacrolimus in a liquid first composition at a temperature below the melting point of the tacrolimus, wherein the first composition comprises (i) polyethylene glycol having an average molecular weight of from 3,000 to 35,000 and (ii) poloxamer;

ii) spraying the resulting first composition onto a solid second composition having a temperature below the melting point of the first composition,

iii) adding hydroxypropyl methylcellulose and optionally additional release-rate modifiers to the product of step (ii),

iv) forming a solid dosage form from the product of step (iii), wherein the solid dosage form comprises from about 10 to about 60% w/w of hydroxypropyl methylcellulose.

87. (New) The method according to claim 86, wherein the hydroxypropyl methylcellulose is added in a fluid bed.

88. (New) The method according to claim 86, wherein the polyethylene glycol, poloxamer, and hydroxypropyl methylcellulose form a matrix.

89. (New) The method according to claim 86, wherein the solid dosage form is a tablet.

90. (New) A solid dosage form prepared by the method of claim 86.